REMARKS

Claims 1-274 and 276-282 have been canceled. As will be discussed in further detail below, claim 275 has been amended to more distinctly claim that which Applicants regard as the invention. Claims 284-289 have been added to recite specific embodiments. Claims 289 and 290 are directed to a method for using the composition of claim 275. As will be discussed in further detail below, amended claim 275 and new claims 283-289 do not contain new matter and are supported by the specification.

1. The Rejections Under 35 USC §112, First Paragraph

Claims 275, 276, and 283, are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. It is asserted that the basic terms of claim 275 are considered to be so broad as to render one of skill in the art reading such a claim and attempting to envision the claimed invention unable to do so. Specifically, the Office Action states

> The specification discloses that a monomeric unit comprises a compound and a polymer. The specification does not define these broad terms, but merely lists what may be embraced by their recitation. Furthermore, the terms used to define these broad terms are themselves very broad. For example, the specification teaches that the compound may be a naturally occurring compound, a modified natural compound, a synthetic compound, or a recombinantly produced compound, or a combination of such compounds. More specifically, the compound can comprise a protein, monosaccharide, oligosaccharide, polysaccharide, fatty acid, fatty acid ester, or a polynucleotide, a hormone, a polyclonal or monoclonal antibody, f(ab) fragment, a growth factor, a lymphokine, a cytokine, a cellular matrix protein, a ligand, vector, bacterium, or virus, or a combination of these. This list refers only to the compound of the monomeric unit, although certain examples from a list of compounds would certainly also fall within the definition provided for a polymer, such as proteins, nucleic acids, antibodies, cytokines, lymphokines, etc. Virtually any biological molecule fall is considered to fall under such scope.

It is further stated in the Office Action:

> It is granted that there is some discussion and apparent contemplation that the polymer may be a polynucleotide. However, as stated in the specification, the polymer can also comprise a protein, antibody, cytokine, or lymphokine, etc. without limit.

Applicants respectfully traverse the rejection. As argued in the previous response, an adequate description of the multimeric compositions of the present invention and representative number of species have been provided. Furthermore, in addition to the Example, several examples of compounds and polymers as well as compound-polymer and polymer-matrix combinations have been provided in the specification.

However, in order to advance prosecution claim 275 has been amended to recite that the monomeric unit comprises two elements: (a) a protein which may be an antibody, a lymphokine, a cytokine, a hormone, a cellular matrix protein and growth factor and (b) a polymer selected from the group consisting of a polysaccharaide, polynucleotide or polypeptide and that the monomeric unit is attached to a binding matrix, through the polymer. Amended claim 275 is supported by the specification in the paragraph bridging pages 70-71 where it is stated:

> A monomeric unit is an entity comprised of two elements. Said first element is a compound. Said second element is a polymer (or oligomer) capable of noncaovalently binding, complexing or hybridizing either to the polymer or oligomeric element of a second monomeric unit or to the polymer or oligomer that makes up a binding matrix. Among others, the monomeric unit can be selected from a naturally occurring compound, a modified natural compound, a synthetic compound and a recombinately produced compound or combinations of such compounds.

Further support can be found in the first full paragraph of page 71 where it is stated:

> Said compound may be an analyte specific moiety that is capable of recognizing and binding to a component in a biological system in vivo or in vitro. ....The compound could be naturally occurring a modified natural compound, a synthetic compound or a recombinant product. It could be a polyclonal or monoclonal antibody, complete protein

> chains or f(ab) fragments, from human or other species; it could be a lymphokine, cytokine, hormone (e.g., insulin), or growth factor (e.g., erythropoietin) or a cellular matrix protein (e.g. fibronectin);....

Support for the polymer and binding matrix may be found in the paragraph bridging pages 72 and 73:

> The binding matrix is an entity comprised of a linear or branched polymeric compound that has more than one portion of a linear segment that is capable of noncovalent binding to a linear segment of a polymer of a monomeric unit. The linear segment could be comprised of a homopolymer, heteropolymer or co-polymer , a synthetic polymer, a natural polymer, a polynucleotide, modified polynucleotide, or polynucleotide analog or polyionic compound. Thus the binding matrix can comprise or take it s selection form a polypeptide, a polynucleotide and a polysaccharide or any combination.

There is further support for claim 275 in figures 21, 22 and 23.

It is Applicants position that given the amendment of claim 275 and the above arguments, one of ordinary skill in the art would be able to envision a representative number of structures that fall within the scope of the first and elements recited. Therefore, Applicants respectfully request that the rejection be withdrawn.

2. The Rejections Under 35 USC §102

Two references have been cited, Curiel et al., US Patent No. 5,521,291 (hereinafter "Curiel et al.) and Leibold et al., 1988, Proc. Natl. Acad. Sci. 85:2171-2175 (hereinafter "Leibold et al."). Each is discussed below.

2.1 Curiel et al.

Claims 275, 276, and 283 are rejected under 35 U.S.C. 102(e) as being anticipated by Curiel et al. (U. S. Patent Number 5,521,291). The Office Action specifically states:

> Applicants argue that if the adenovirus were the binding matrix and antibody/polylysine complex were the monomeric unit, that the polylysine moiety would not be bound to the adenovirus via either hydrogen bonds or dipole dipole interactions, and that therefore Curiel cannot anticipate. This is agreed. Applicants also argue that a second interpretation of Curiel set forth by the examiner could also not anticipate the instant claims, whereby the monomeric unit is the adenovirus and the antibody/polylysine complex is the binding matrix, because the monomeric unit would not comprise a polymer and a compound. This is not adopted, however, because the breadth of the term "polymer" and "compound" is such that the adenovirus could comprise a monomeric unit; an adenovirus comprises proteins, which are polymers, as well as numerous compounds, such as nucleotides.
>
> Furthermore, this is not the only interpretation of Curiel that would anticipate the instant invention. For example if the monomeric unit comprising the compound and polymer were considered to be the antibody/polylysine complex of Curiel, wherein the antibody is the compound and the polylysine is the polymer, the plasmid DNA could therefore be the binding matrix, in which case the polylysine (i.e. the polymer) associates with plasmid DNA (i.e. the polymer of the matrix) via a combination of dipole interactions and hydrogen bonding. By this interpretation, the compound comprises a protein (consistent with claim 276 of the instant specification), whereas the polymer is polylysine (consistent with page 74 of the instant specification), and the matrix is a polynucleotide (consistent with page 73 of the instant specification). Finally given this interpretation more than one compound is attached to the polymer, as specified in claim 283. Accordingly, Curiel, by this interpretation, is considered to anticipate the instant invention.

Applicants respectfully traverse the rejection. However, in order to advance prosecution, claim 275 has been amended to recite that the monomeric unit contains two elements: (a) a protein which may be an antibody, lymphokine, cytokine, hormone, cellular matrix protein or growth factor and (b) a polymer which may be a polynucleotide or polysaccharide. The binding matrix, which may be a polypeptide,

polynucleotide or polysaccharide or any combination thereof is attached to the second element of the monomeric unit, a polynucleotide or polysaccharide. The binding matrix is bound to the polymer via hydrogen binding or dipole interactions.

In the previous Office Action, two interpretations of Curiel et al. were set forth. Claim 275 as amended would not be anticipated by Curiel et al. since Curiel et al. does not contain each and every element of claim 275 no matter which interpretation is used. Each is discussed below:

A. Interpretation #1: Adenovirus is the binding matrix and the antibody/polylysine is the monomeric unit

Interpretation #1 would not be encompassed by amended claim 275 for two reasons. First, although the antibody could be a member of the monomeric unit, the polylysine could not. This is because amended claim 275 recites that the polymer is selected from the group consisting of a polynucleotide and polysaccharide. Secondly, as conceded in the Office Action, the polylysine moiety would not be bound to the adenovirus via either hydrogen bonds or dipole dipole interactions.

B. Interpretation #2: The monomeric unit is the antibody/polylysine complex where the antibody is the compound, polylysine is the polymer and plasmid DNA is the binding matrix where the polylysine associates with plasmid DNA via a combination of dipole interactions and hydrogen bonding.

Interpretation #2 would also not be encompassed by claim 275 as amended. This is because, as noted above, although the antibody could be a member of the monomeric unit, the polylysine could not. This is because amended claim 275 recites that the polymer is selected from the group consisting of a polynucleotide and polysaccharide.

2.2 The Rejection Over Leibold et al.

Claims 275, 276, and 283 are rejected under 35 U.S.C. §102(b) as being anticipated by Leibold et al. The Office Action specifically states:

> Leibold et al. teaches a gel shift assay, wherein proteins (i.e. a compound) cross- linked to polynucleotides (i.e. a polymer) are run through a gel (i.e. a binding matrix comprising a polymer). One of ordinary skill would understand that the polynucleotide/ protein monomer is bound to the gel non-covalently, through a complex combination of interactions that is considered to include both hydrogen bonding and dipole interactions. This is particularly true in view of the broad claim recitation that the binding be through "dipole interactions". Interpreted broadly, "dipole interactions" can involve any two molecules that interact, since every molecule has a dielectric constant which gives rise to said dipole. Thus any molecules that interact, as the monomer and gel of Leibold clearly do, involves interactions of their dipole moments (i.e. their dielectric constants). Therefore, Leibold et al. is considered to teach all the limitations of the claims above.

Applicants respectfully traverse the rejection. However, in order to advance prosecution, claim 275 has been amended to advance prosecution and to more distinctly claim that which Applicants regard as their invention. Claim 275 as amended would not be anticipated by Leibold et al. This is because Leibold et al. does not contain each and every element of amended claim 275. Specifically, in Liebold the monomeric unit is the protein (compound)/polynucleotide (polymer) complex and the binding matrix is the polyacrylamide gel. Although the monomeric unit in the recited invention could be a protein/polynucleotide complex, the binding matrix may only be a polynucleotide or polysaccharide, **not** a polyacrylamide gel.

In view of the above amendments and arguments, it is asserted that the rejections of claim 275 over 35 USC §102(b) has been overcome. Applicants assert that the rejection of claims 276 and 283 have also been overcome. Claim 276 has been canceled. Claim 283 depends from claim 275. Therefore, given that the rejection of claim 275 has been overcome, the rejection of claim 283 has been overcome as well. New claims, 284-289, which depend from claim 275 would also not be anticipated by the cited references. Therefore, Applicants respectfully request that the rejections under 35 USC §102(b) be withdrawn.

3. The Rejections Under 35 USC §112, First Paragraph

Claim 283 has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action states:

> Claimed 283 is drawn to the composition of claim 275, "wherein more than one compound is attached to a polymer". While there are two polymers recited in claim 275, claim 283 is interpreted as claiming, "more than one compound attached to either of such polymers, and is therefore not considered indefinite. However, Applicants have failed to indicate where support exists for more than one compound attached to any polymer of claim 275. Applicants of merely indicated that "the new claims are supported by the specification", and that "[n] new matter has been added."

Applicants respectfully traverse the rejection. Before, responding to the rejection, Applicants note that claim 283 has been amended to recite that more than one protein in the first element of the monomeric unit of the present invention can bind to the polymer in the second element of said second monomeric unit. Amended claim 283 is supported by the specification on page 80 where it is stated:

> Another useful multimeric composition comprises more than one component attached to a charged polymer. The charged polymer is selected form a polycationic polymer, a polyionic polymer, a polynucleotide, a modified polynucleotide and a polynucleotide analog as well as combinations of the foregoing. Such a component can comprise a protein, e.g., an antibody (polyclonal or monoclonal), an $F(ab')_2$ fragment or both. The antibody can be further complexed with a target comprising an enzyme.

In view of the amendment of claim 283 and the above arguments, Applicants assert that the rejection of claim 283 under 35 USC §112, first paragraph has been overcome. Therefore, Applicants respectfully request that the rejection of claim 283 under 35 USC §112, first paragraph be withdrawn.

Summary and Conclusions

In view of the above amendments and remarks, it is asserted that the currently pending claims are in condition for allowance.

If a telephone conversation would further the prosecution of the present application, Applicants' undersigned attorney request that he be contacted at the (914) 712-0093.

Respectfully submitted,

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Cheryl H. Agris

Cheryl H. Agris, Reg. No. 34,086